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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.         | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------------|------------------|
| 10/528,275  | 08/18/2005  | Johannes Jung        | 3283-PAT                    | 2960             |
| 30084   | 7590        | 03/23/2007           |                             |                  |
| DONN K. HARMS<br>PATENT & TRADEMARK LAW CENTER<br>SUITE 100<br>12702 VIA CORTINA<br>DEL MAR, CA 92014 |             |                      | EXAMINER<br>ADAMS, AMANDA S |                  |
|   |             |                      | ART UNIT                    | PAPER NUMBER     |
|   |             |                      | 3731                        |                  |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 03/23/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/528,275 | <b>Applicant(s)</b><br>JUNG, JOHANNES |  |
|                              | <b>Examiner</b><br>Amanda Adams      | <b>Art Unit</b><br>3731               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 13-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-27 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 13 is objected to because of the following informalities: "unitary structure being self-expanding stent" in line 4, and "...said wall segments, said voids..." in lines 10-11 are incorrect grammar. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "more or less rectilinear" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. "More or less" does not provide a quantitative degree as to how rectilinear the spring devices are.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 13-21 and 23-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Ogi et al (US 5,925,061), hereinafter referred to as Ogi.

6. Regarding claims 13 and 23, Ogi discloses the invention substantially as claimed including a stent formed as a unitary structure from a shape memory material (col. 6, lines 14-19) and being self-expanding, said unitary structure being a tube shaped body defined by a curved planar sidewall surrounding an axial interior along a length, said sidewall having voids formed therein defining a plurality of adjacently positioned ring shaped elastic wall segments, each having a radial elastic structure, said wall segments and said voids defining gaps separating said wall segments, a plurality of connector devices in a communication across said gaps linking adjacently positioned said wall segments, said connectors having a substantially "S" shape at a central portion of said communication (fig. 5a); said connector devices aligning along a length of said body to form at least one continuous longitudinal flange (the length of the flange and the length of the body the flange is aligned along are not defined, therefore any connector piece [18] meets this limitation); said flange providing means to maintain said length of said stent under tensile or compressive stress (col. 5, lines 17-21); and said S shape of said connectors providing means for absorbing a compressive stress in the axial direction or a tensile stress in the longitudinal direction (col. 4, lines 23-34; fig. 1).

7. Regarding claims 14 and 15, Ogi discloses that the wall segments have first and second spring devices arranged in alternate fashion at an angle to each other wherein the spring segments are more or less rectilinear (fig. 1).

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8. Regarding claims 16 and 17, Ogi discloses that the connector devices communicate in between only the first spring devices or only the second spring devices (fig. 1).

9. Regarding claims 18-21, Ogi discloses that several longitudinal flanges are parallel to each other at determined distances from each other in a helical formation along said length of said sidewall (fig. 1 [18]; if you follow the placement of the flanges as you move axially from one end of the stent to the other, you can see that they are positioned in a helical pattern).

10. Regarding claim 24, Ogi discloses a unitary structure that is capable of being expanded with a balloon catheter (any stent is capable of balloon expansion, whether or not a balloon catheter is required to expand it).

11. Regarding claim 25, Ogi discloses that the shape memory material of the stent is Nitinol (col. 6, lines 14-19).

12. Regarding claim 26, Ogi discloses that the stent can also be made of a plastic (col. 6, lines 14-19).

13. Regarding claim 27, Ogi discloses that the sidewall is machined to a smooth polished surface (col. 5, lines 62-65).

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogi et al (US 5,925,061).

16. Ogi discloses first and second spring devices have a width and that the connector devices have a width, but fails to disclose the differences in width relative to each other. However, the process of making the device of Ogi allows for the widths chosen to be different from each other (col. 5, line 45 – col. 6, line 13). Having a connector width greater than that of the first and second spring devices allows the stability of the device to be improved and reduces the chances of it being damaged. Therefore it would have been obvious to have the connector width greater than that of the spring devices.

### ***Response to Arguments***

17. Applicant's arguments with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection.

18. Additionally, the arguments were not found to be persuasive with respect to claims 13-27, because the claims only specify that the stent is a unitary structure in a tube shape. This can be made in a number of ways, and the claim does not specify a method of making. Therefore it does not matter if the stent was an elongate tube wherein the gaps have been etched out, or if it was a plurality of struts welded together.

### ***Conclusion***

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19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- a. US 6,488,703,
- b. US 6,520,987,
- c. US 6,200,334,
- d. US 5,980,553,
- e. US 6,730,116,
- f. US 7,153,322.

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Adams whose telephone number is (571) 272-5577. The examiner can normally be reached on M-F, 8:00am-5:00pm, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ASA ASA 3/13/07

  
GLENN K. DAWSON  
PRIMARY EXAMINER